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Perspective

RCJ Journal of the Academy of Public Health

It’s time to rethink, recalibrate, and redistribute NIH Funding

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Submitted: Apr 2, 2025 | Published: Apr 15, 2025 |
DOI: https://doi.org/10.70542/rcj-japh-art-1yh5z28

Abstract

The National Institutes of Health (NIH) awards billions of dollars in grants for medical research.[1] But is the American taxpayer getting the best bang for the buck? Advancing science is a worthy goal, but perhaps the proper goal should be advancing science to advance patient care. That's basic science and translational research. How can we explain this yawning chasm in program funding? Between 2010-2019, 83% of NIH grants (totaling $156 billion) were for basic research and 17% ($31 billion) were for translational research. Considering this vast financial differential in funding, it's relevant to consider if the huge differential between basic and translational research is appropriate. Is basic research nearly 50% more important than translational research?

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Introduction

Per a recent article in the Journal of the American Medical Association, between 2010-2019, NIH funding for basic research (also known as "curiosity-based science") contributed to 354 of 356 (99.4%) of drugs approved by the Food and Drug Administration (FDA).[2] While there are many caveats, "the NIH spent $1.44 billion per approval on basic or applied research for products with novel targets."

Further, "Private sector investment and returns are classically viewed as the primary driving force for innovation. Evidence also shows that public sector investments in basic and applied biomedical research, including those from the National Institutes of Health (NIH), contribute substantively to the emergence of new drugs and drug-related patents. Recent economic studies have recognized the government's contributions to pharmaceutical innovation by contextualizing government as an "early-stage investor and government funding for research as an investment."

What this statement doesn't take into consideration is that by combining funding for "basic and applied" science grants and, similarly, "drugs and drug-related patents," it dilutes both the methodology and conclusions of the study.[3] Let's start by defining the nomenclature.

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ISSN: 3067-6614 (Online)

"Basic" research is early-stage science focusing on fundamental processes and building blocks of disease.[4] "Applied" research focuses on applying scientific discoveries to real-world problems and improving health outcomes, often through clinical trials and developing new treatments. It is also known by the moniker of "translational" research. Both categories are important because you cannot advance patient outcomes without both.[5]

Between 2010-2019, 83% of NIH grants (totaling $156 billion) were for basic research and 17% ($31 billion) were for translational research.[6] Considering this vast financial differential in funding, it's relevant to consider if the huge differential between basic and translational research is appropriate. Is basic research nearly 50% more important than translational?

A major difference between the two types of research is that while basic research is generally wholly academic (university-based) in nature, translational research often demands cooperation between academics and the innovative biopharmaceutical sector. If the goal of every NIH grant is to advance medical science, is this "grant gap" appropriate? This question is particularly timely as Dr. Jay Bhattacharya[7] begins his tenure as the agency's new Director.

Addressing the NIH “Grant Gap”

Advancing science is a worthy goal but, perhaps, the proper goal should be advancing science to advance patient care." That's basic science and translational research. How can we explain this yawning chasm in program funding?

The Occam's Razor[8] explanation is that the NIH can only approve grants that they are asked to review. In other words, the overwhelming number of grant requests are for basic science research. Another way to define "basic science research" is research that isn't only exclusive to academic researchers but that purposely excludes intramural cooperation with the biopharmaceutical industry. Such puritanical attitudes are churlish, outdated, and contrary to the scientific tenet of cooperation. It also helps to explain another problem with university research funding - NIH funding assists academics in their personal quests for professional advancement (larger labs, increased staffing and, most notably, gaining tenure).[9]

Why aren't more academic researchers seeking more translational program funding partnerships from potential industry partners? One reason, as the JAMA research suggests, is that they don't have to. With every doubling of the NIH budget, the incentives for translational industry partnerships decreases. Academics are fishing where the fishing is most abundant. Another piece of the puzzle is program accountability. For academics, "success" doesn't mean "We solved the problem." It means "Our initial experiments are complete." Research funded by innovator biopharmaceutical companies have more market-driven, stepwise structure, where conclusions are more than just "we need to do more research." These two very different views of accountability are a key problem in bridging the desire (and therefore the funding) for more academic translational research programs. The question remains: if NIH-funded basic research programs never fail, how can the NIH define success?

The Issue of Indirect Costs

One of the issues driving the future of funding conundrum is the issue of "indirect costs." For every dollar the NIH awards in grants, it has historically provided 69 cents for grantee "overhead" to cover the facilities and administration infrastructure. The NIH negotiated indirect cost rates individually for each university in a complex, resource-consumptive process. After a university's rate was determined, that rate applied for the next three to four years to every NIH research grant that that a university might receive, as well as to grants from other federal agencies.[10]

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As of February 2024, those indirect cost rates were to be capped at 15%[11] of the direct cost of a grant and not be negotiated on a university-by-university basis. Further, the 15% indirect cost-rate cap would apply to grants already under way, not just to future ones. Not surprisingly, this policy is being litigated.[12] In response to a lawsuit filed by university associations and major research centers, Judge Angel Kelley (U.S. District Court, Boston) ordered the Trump administration to hold off on these cost-cutting initiatives. The status quo is fighting for its life. In the private sector, the average charge for indirect overhead costs is typically between 25% and 33% of the total amount of a grant.[13] Doubling down on litigation to maintain "the good old days" of 69% overhead funding is a high-risk strategy. In the current political, social, and economic environment, project development and funding diversification deserve more serious and careful consideration.

Facilitating Product Innovation Through Inter-Agency Cooperation

NIH and the Food and Drug Administration (FDA) are sister agencies within the US Department of Health and Human Services. NIH is a funder/partner while FDA is a regulator/partner. Unfortunately, the expertise and experience of one isn't always taken into consideration or appreciated by the other. One example is the design and execution of clinical trials. Even when NIH funds grants for translational research, many of which include human trials, they often fail to reach out to the FDA to vet the prospective grantee's technical assumptions - decreasing the ability to validate relevant findings and, potentially, putting clinical trial participants at risk. Other areas of relevant, but siloed knowledge is the FDAs expertise in biomarkers, real world evidence, and benefit/risk analysis.

While parts of this problem can be laid at the feet of of inter-agency jealousies and "not invented here" attitudes, the real obstacle is the lack of leadership from the office of the HHS Secretary. Since inter-agency cooperation isn't succeeding organically, it's time for top-down initiatives led by an HHS "Innovation Czar." Such cooperation will act as a force multiplier, helping to make the recipients of NIH grants more likely to succeed. A good first step would be for the NIH to consider mandatory cross training for their internal teams and external grantees in the processes, procedures, and evidentiary standards of the FDA.

Narrowing the Grant Gap: A Partnership Funding Model

Potentially fewer NIH-funded grants and lower reimbursement rates for indirect costs are both very unsubtle signals that academic researchers should look to sources other than NIH for project funding. The obvious opportunity lies with more and more regular partnerships with the biopharmaceutical industry. It should also drive innovative thinking inside the NIH grant-making apparatus. Perhaps the NIH should create a category of "matching grants" whereby government support is contingent on an applicant's first receiving equal support from private sources (such as foundations and the biopharmaceutical industry). To accelerate this model, university departments should also break with tradition and make clear that funding other than that received from the NIH is considered "tenure-worthy."

Such a paradigm shift requires abandoning the shibboleths of traditional research purity such as:

-"The pursuit of knowledge can't be put on a corporate timeline."

-"The academic research is incompatible with the corporate thirst for profit."

-"Industry partnerships will curtail academic freedom."

These excuses presuppose that biopharmaceutical companies have neither interest in nor use for academic research of either the basic or translational variety. There is no evidence to support this urban legend. It takes two to tango.

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ISSN: 3067-6614 (Online)